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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/665,552 | 09/22/2003 | Johannes Bartholomaeus | 029310.50777CP | 6176 |
| 23911 7590 05/06/2010 CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300 | | | | |
| EXAMINER | | | | |
| TRAN, SUSAN T | | | | |
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| 1615 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/665,552

Applicant(s)

BARTHOLOMAEUS ET AL.

Examiner

S. TRAN

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 9-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9-26 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1-4, 6, 7, 9-26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss et al. US 4,690,927, in view of Mok et al., and Addicks et al. US 5,041,430, and Bergamini et al. US 5,597,560 or Bodley et al. US 5,679,660.

Voss teaches a pharmaceutical dosage form comprising mixture of diclofenac sodium and salt of codeine in a weight ratio of about 1:1 to 3:1 (abstract; and claims 1-3). The dosage is suitable for oral administration in the form of granule, dragee, tablet, layered tablet, and capsule (column 2, lines 11-64). The two active substances can be formulated in separate layers in a tablet (ID). The final dosage form can be film coated with hydroxypropylmethyl cellulose (example 1).

Voss is only deficient in the sense that Voss does not teach the use of tramadol.

Mok teaches combination of tramadol and diclofenac useful for the treatment of pain (abstract).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the dosage form of Voss to include the combination of tramadol and diclofenac in view of the teachings of Mok to obtain the claimed invention. This is because Mok teaches that combination of tramadol and diclofenac provides the best pain relief, because Mok teaches that combination of tramadol and diclofenac is known in the art and has low side effects (see abstract), and because Voss teaches the desirability of combining diclofenac with an opioid analgesic compound to achieve a more intense therapeutic effect but eliminating side effects (column 2, lines 5-10).

Voss further does not explicitly teach the separation of two active agents.

Addicks teaches a dosage form comprising combination of at least two active agents, wherein the active agents are separated by a coating layer to minimize physical contact between the active agents to prevent chemical interaction (columns 4-5). Thus, it would have been obvious to one of ordinary skill in the art to include the separating layer between the diclofenac and the codeine to obtain a more stable composition. This is because Addicks teaches a dosage form suitable for the delivery of at least two active agents that are known to have potential for chemical interaction (column 3, lines 65 through column 4), and because diclofenac is known in the art to exhibit interaction with quite a number of active agents. See for example Bergamini et al. at column 7, lines 20-30; and Bodley et al.

Claims 1-4, 6, 7, 9-26 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa US 5,516,803, in view of Mok et al., and Addicks et al. US 5,041,430 and, and Bergamini et al. US 5,597,560 or Bodley et al. US 5,679,660.

Raffa teaches a composition comprising combination of tramadol and an NSAID (abstract; and column 3, lines 15-59). NSAID includes diclofenac (column 4, lines 29-37).

It is noted that Raffa teaches diclofenac among a number of NSAID.

However, combination of diclofenac and tramadol is known in the art. See Mok's abstract for example. Mok teaches a combination of tramadol and diclofenac for the treatment of pain.

Thus, it would have been obvious to one of ordinary skill in the art to optimize the composition of Raffa to include the combination of tramadol and diclofenac in view of the teachings of Mok to obtain the claimed invention. This is because Mok teaches that combination of tramadol and diclofenac provides the best pain relief, because Mok teaches that combination of tramadol and diclofenac is known in the art and has low side effects (see abstract), and because Raffa suggest combining tramadol and NSAID that could include diclofenac.

Raffa does not teach the separation of two active agents.

Addicks teaches a dosage form comprising combination of at least two active agents, wherein the active agents are separated by a coating layer to minimize physical contact between the active agents to prevent chemical interaction (columns 4-5). Thus, it would have been obvious to one of ordinary skill in the art to include the separating layer between the combination of active agents such as tramadol and diclofenac to obtain a more stable composition. This is because Addicks teaches dosage forms suitable for the delivery of at least two active agents that are known to have potential for chemical interaction (column 3, lines 65 through column 4), and because diclofenac is known in the art to exhibit interaction with quite a number of active agents. See for example Bergamini et al. at column 7, lines 20-30; and Bodley et al.

Response to Arguments

Applicant's arguments filed 01/25/10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615